HON. JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

B. E. and A. R., on their own behalf and on behalf of all similarly situated individuals,

Plaintiffs,

v.

DOROTHY F. TEETER, in her official capacity as Director of the Washington State Health Care Authority,

Defendant.

NO. 2:16-cv-00227

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Noted for Consideration: April 15, 2016

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

Table of Contents

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

Table of Authorities

CASES

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

STATUTES

REGULATIONS

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

OTHER AUTHORITIES

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

I. INTRODUCTION

Plaintiffs are Washington Medicaid enrollees who have contracted Hepatitis C virus ("HCV"), a blood-borne, communicable disease that afflicts millions of Americans. After many years without effective treatment, there is now a cure for plaintiffs and others like them. Eradication of this potentially lethal disease is now possible. Despite the medical breakthrough, the Washington State Health Care Authority ("WHCA") does not cover the treatment for all individuals infected with HCV. Instead, it excludes all Medicaid recipients from the treatment, except those few who have suffered the most liver damage from the disease. WHCA limits coverage of the cure solely because it is expensive. This rationing of care violates federal law.

The standard of care for treating Hepatitis C virus is established by the American Association for the Study of Liver Disease (AASLD)[1] and the Infectious Diseases Society of America (IDSA).[2] The two organizations have jointly issued extensive treatment guidelines for HCV which recommend treatment for virtually all infected individuals:

> ***Recommendations for When and in Whom to Initiate Treatment***
>
> ***Treatment is recommended for all patients with chronic HCV infection,*** except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.
>
> Rating: Class I, Level A

Declaration of Robert G. Gish, M.D., *Exh. B* (emphasis in original and added). Despite the medical evidence, WHCA asserts that it can apply a blanket exclusion of coverage for thousands of Medicaid enrollees with HCV, and make them wait an indefinite period of time, perhaps years, for treatment. There is no clinical justification for this "wait and see" approach.

---

[1] AASLD was founded in 1950 and is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. *See* http://www.aasld.org/about-aasld.

[2] IDSA was founded in 1963 and represents physicians, scientists and other infectious disease specialists promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases. *See* http://www.idsociety.org/About_IDSA/.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

WHCA's exclusionary policy is an outlier. In the past year, many Washington insurers and third-party payors voluntarily removed similar restrictions in their coverage of HCV treatment, including Premera BlueCross, Aetna, United Healthcare, Medicare, the Veterans Administration, among others. *See* www.premera.com/medicalpolicies/5.01.606.pdf (Premera's policy); www.aetna.com/products/rxnonmedicare/data/GI/hepatitis_c.html (Aetna policy); www.najap.org/2014/HCV/PA_Notification_Harvoni_101414.pdf (United Healthcare policy); www.hepatitis.va.gov/pdf/treatment-considerations02-15-12-15.pdf (Veterans Administration policy); http://www.npr.org/sections/health-shots/2014/05/16/313025946/medicare-eases-restrictions-on-pricey-hepatitis-c-treatment (Medicare policy). When lawsuits were filed against Regence BlueShield, BridgeSpan and Group Health Cooperative regarding their similar exclusionary policies, the insurers changed their practices within a matter of weeks. Hamburger Decl., ¶ 11. Now, virtually all insured patients with HCV in Washington have access to this medically necessary treatment. The only ones left behind are Washington's Medicaid enrollees and those covered by WHCA's Public Employee Benefit Board (PEBB) program. WHCA's exclusions are clinically indefensible.

WHCA's rationing is not permitted under Medicaid law. As a condition of participating in the program and receiving federal matching funds, WHCA is required to provide "medical assistance," including payment for FDA-approved, covered prescription drugs, to all Medicaid enrollees when the treatment is "medically necessary." *Alvarez v. Betlach*, 572 F. App'x 519, 520-21 (9th Cir. 2014). WHCA cannot make some enrollees wait until their health is significantly damaged before they are covered for curative treatment. *See* 42 U.S.C. § 1396a(a)(8) (states must provide "medical assistance" including access to medically necessary prescription drugs with "reasonable promptness" typically considered 90 days). Nor can WHCA pick and choose among comparable Medicaid enrollees, deeming a few worthy of a cure, while leaving thousands without it. *See* 42 U.S.C. § 1396a(a)(10)(B)(i).

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

Plaintiffs and the putative class will suffer irreparable harm if they are forced to wait until they sustain liver damage before they can get treatment. Waiting until Medicaid enrollees' liver is significantly damaged before providing coverage for a cure increases their risk of serious health problems, including, but clearly not limited to, liver disease, cancer and death. Plaintiffs' expert, Robert Gish, M.D., a nationally renowned authority on viral hepatitis, explains:

> [I]t is critical that patients with chronic HCV be treated ***before*** the liver has been damaged by the virus. Delaying treatment and observing an individual while that individual's liver degrades to a fibrosis score of F3 or F4 significantly increases the risk of death from cancer or liver failure. It also significantly increases the chance that the individual will require a liver transplant. ... Observation not only causes irreversible liver damage, it damages other organs as well because HCV is not just a disease that affects the liver. It is a systematic disease that, while untreated, can cause heart attacks, fatigue, joint pain, depression, sore muscles, arthritis, and, at times, premature death.

Gish Decl., ¶ 17. The AASLD-IDSA concurs: "Untreated HCV has been linked to many causes of death, such as liver cancer and kidney problems…" *Id., Exh. C.* In addition, the risk of heart disease, lymphatic cancers, kidney damage, heart attacks, immune-related disease, diabetes, insulin resistance, nerve damage, jaundice, joint pain, depression, sore muscles, arthritis and premature death are all significantly increased when HCV is left untreated. Gish Decl., ¶¶ 3, 17, *Exh. L;* www.cdc.gov/hepatitis/statistics/index.htm.

A balancing of the interests at stake here – between the WHCA's fiscal concerns and plaintiffs' need for an immediate cure for this devastating, communicable virus – weighs heavily in favor of preliminary injunctive relief. *Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983). The Court should grant a preliminary injunction ordering WHCA to repeal the blanket exclusions contained in its February 25, 2015 HCV treatment policy and allow all Medicaid enrollees diagnosed with HCV to have their requests for HCV treatment be reviewed for medical necessity, consistent with the AASLD-IDSA Guidelines and existing state and federal Medicaid law.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

II. FACTUAL BACKGROUND

A. Hepatitis C Virus Is a Widespread, Contagious and Deadly Disease.

Hepatitis C is a chronic, contagious disease of the liver. It is estimated that approximately five million individuals in the United States are living with this chronic disease, including 100,000 Washingtonians. Gish Decl., ¶ 3; www.doh.wa.gov/Portals/l/Documents/Pubs/150-063-HepatitisCStrategicPlan2014.pdf.

As it progresses, HCV causes severe liver damage, among the many other effects that accompany a chronic inflammatory disease. This progressive damage, known as "fibrosis," is scored on an ascending fibrosis score of F0 (no liver damage) through F4 (cirrhosis of the liver). HCV is both widespread and deadly – over 20,000 people in the United States die every year due to liver disease caused by HCV. Gish Decl., ¶ 3; *see* http://www.cdc.gov/hepatitis/Statistics/index.htm (last visited March 9, 2016). Even before progressing to an advanced stage, however, HCV puts individuals at risk of multiple severe and life-threatening conditions. Gish Decl., ¶¶ 3, 17. Statistics from the Centers for Disease Control and Prevention indicate that up to 70% of those with HCV will develop chronic liver disease, 40% will develop cirrhosis, and more than 5% will develop liver cancer. *Id.*, ¶ 3.[3]

For many years, the main treatment for HCV was a three-drug treatment containing boceprevir, interferon and ribavirin. Gish Decl., ¶ 6; *see* Dkt. No. 16, ¶ 13. The treatment resulted in, at best, a 70% cure rate. Gish Decl., ¶ 6. Patients experienced severe side effects, including anemia, insomnia, anxiety, depression, nausea, bone pain, muscle, liver failure, joint pain, memory loss and death. *Id.*, ¶ 6, *Exh. K.* Indeed, the side effects were so severe, and the cure rate

[3] Regardless of the specific progression of the disease, each person infected with HCV is benefited by immediate treatment, both in its effect on the liver and in its extrahepatic effects. *See* AASLD-IDSA, *Recommendations for Testing, Managing, and Treating Hepatitis C*, http://www.hcvguidelines.org (last visited March 9, 2016) ("AASLD-IDSA Guidelines") at 30 ("[F]rom a medical standpoint, data continue to accumulate that demonstrate the many benefits, within the liver and extrahepatic, that accompany HCV eradication."). For ease of reference, excerpts from the AASLD-IDSA Guidelines are also attached to the Declaration of Eleanor Hamburger, *Exh. A.*

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

so low, that many patients were unwilling to take the medications. WHCA admits that it never rationed the prior three-drug treatment based upon fibrosis score.[4] Dkt. No. 16, ¶ 13.

B. New "Breakthrough" Treatment Can Eradicate HCV.

In 2011, however, the FDA began approving a series of oral medications capable of curing the infection. These drugs, known as Direct-Acting Antivirals ("DAAs"), were designated as "breakthrough therapies" by the FDA, a classification reserved for drugs that have proven to provide substantial improvement over available therapies for patients with serious or life-threatening diseases. Harvoni (ledipasvir-sofosbuvir) ("Harvoni"), a DAA treatment approved by the FDA on October 10, 2014, has a success rate of achieving sustained virologic response ("SVR") of nearly 100% with little to no side effects. *Id.*, ¶ 7.[5] WHCA does not dispute the efficacy of DAA treatment. *See* Dkt. No. 16, ¶¶ 14, 16. Accordingly, DAA treatments provide a very real opportunity to eradicate the HCV virus, so long as patients receive timely treatment.

C. Clinical Standards Mandate Treatment for Virtually All HCV Patients.

The AASLD and the IDSA have issued evidence-based treatment recommendations for HCV. *See* Hamburger Decl., *Exh. A (*excerpts from AASLD-IDSA Guidelines). These recommendations, developed by a panel of HCV experts in the fields of hepatology and infectious diseases, specifically confirm that DAA treatment constitutes the standard of medical care for HCV. Gish Decl., ¶ 8. This clinical guidance urges DAA treatment for all patients with HCV regardless of fibrosis score, with the minor exception of patients with short, irremediable life expectancies. *Id.* This position arises, in part, from multiple recent empirical studies that demonstrate greater mortality benefits and treatment success if such treatment is initiated at

---

[4] WHCA likely does not offer this older, less effective treatment as an alternative to Harvoni and other DAAs to B.E., A.R. or others because it is significantly less effective than DAAs. In fact, any doctor prescribing this older therapy would be committing medical malpractice. Gish Decl., ¶ 15 ("In fact, the alternative treatments are so fraught with side effects that treatment with them would be so far below the current standard of care as to constitute medical malpractice.").

[5] SVR means that HCV is undetectable in the subject's blood. An individual achieving SVR is considered to be effectively cured if it persists for six months or longer.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

fibrosis stages prior to F3. Gish Decl., ¶ 8 (citing, *inter alia,* Jezequel, *et al*., "Survival of patients infected by chronic hepatitis C and F0F1 fibrosis at baseline after a 15 year follow-up," 50th Annual Meeting of the European Association for the Study of the Liver (April 22-26, 2015); Zahnd, *et al.*, "Impact of deferring HCV treatment on liver-related events in HIV+ patients," Conference on Retroviruses and Opportunistic Infections (Feb. 23-26, 2015); McCombs, *et al*., "Can Hepatitis C treatment be safely delayed? Evidence from the Veterans Administration Healthcare System," 50th Annual Meeting of the European Association for the Study of the Liver (Apr. 22-26, 2015)). One such study demonstrated that waiting to treat HCV until more severe liver damage has occurred resulted in twice to five times higher rates of liver-related mortality, respectively, compared with treating at fibrosis score F2.[6] Once a person reaches a fibrosis score of F3 or F4 his or her chance of getting liver cancer is so significant to warrant ***twice yearly*** surveillance for liver cancer, even after having been cured with a DAA. *Id.*, ¶ 17.[7]

The benefits of treatment at low fibrosis stages are well documented in the medical literature. *Id.* Delay not only causes irreversible liver damage, it also damages other organs. *Id.* It is a systemic disease that can cause heart attacks, fatigue, diabetes, nerve damage, insulin resistance, joint pain, depression, sore muscles, arthritis, and, at times, premature death. *Id.* "Because of the many benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR, preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications." Gish Decl., ¶ 17, quoting AASLD-IDSA Guidelines at 30. These benefits include improving or preventing extrahepatic complications, including diabetes mellitus,

[6] Gish Decl., ¶ 8 (citing Zahnd, *et al.*).

[7] The AASLD issued a statement on November 16, 2015 condemning the actions of insurers engaged in the practice of delaying DAA therapy. The AASLD maintained that such harmful policies lack any medical justification, risking greater harm to infected individuals and higher rates of transmission to others. Gish Decl., ¶¶ 9-10, *Exh. C.*

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

cardiovascular disease, renal disease, and B-cell non-Hodgkin lymphoma, which are not tied to fibrosis stage. Gish Decl., ¶ 17.

D. WHCA Excludes Coverage of DAAs for Many Medicaid Recipients with HCV.

Washington's Medicaid program is administered by the WHCA. WHCA is responsible for coverage of prescription drugs trough its Medicaid program. WAC 182-530-1000. As a general matter, WHCA covers outpatient drugs in its Medicaid program when: (1) the drug is approved by the FDA and prescribed for a medically accepted indication; (2) the drug is not excluded from coverage under WAC 182-530-2100; (3) the manufacturer has a signed drug rebate agreement with the federal Department of Health and Human Services; and (4) the drug is prescribed by a provider with prescriptive authority. WAC 182-530-2000(1). All of those coverage requirements exist for the treatment at issue in this case.

On February 25, 2015, the WHCA implemented a Hepatitis C Treatment Policy ("WHCA Policy") that provides very limited coverage for DAA treatment for individuals infected with HCV. *See* Dkt. No. 1-1. Under the WHCA Policy, DAA coverage is categorically excluded for all monoinfected patients – patients without another diagnosis, such as HIV – who have a fibrosis score of F0 through F2. Only patients with advanced liver disease (rising to an F3 or F4 fibrosis score), or certain patients with F2 scores who are co-infected with HIV or certain other severe health conditions, are permitted to receive curative treatment. Stated simply, WHCA will not pay for Medicaid patients to be cured of Hepatitis C until the disease has already caused profound damage to the liver.

The WHCA Policy is grossly out of line with the standard of care for treatment of HCV. As discussed above, the AASLD-ISDA recommends treatment with DAAs for virtually all persons diagnosed with HCV. Ironically, WHCA relies upon and repeatedly references the AASLD-IDSA Guidelines in its own HCV policy. *See* Dkt. No. 1-1, p. 6, n.1. But it does not follow them. In short, there is no dispute that the AASLD-IDSA Guidelines – guidelines which mandate coverage for nearly all persons infected with HCV – constitute the standard of care in

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

Washington as well as nationally. Those guidelines unambiguously instruct that all HCV patients, expect those with limited lifespans that cannot be saved by a DAA, should be immediately treated with a DAA.

E. WHCA Excludes Coverage of DAAs to Treat HCV for Many Medicaid Recipients Because of its Cost.

The sole reason for WHCA's exclusionary policy is fiscal, not clinical. DAA treatments like Harvoni are costly.[8] WHCA created its restrictive policy because it feared that providing medically necessary prescription drug coverage to treat all HCV-infected individuals would be cost-prohibitive. Hamburger Decl., *Exh. A*, p. 2.[9] WHCA's Chief Pharmacy Officer Donna L. Sullivan, M.S., Pharm.D., admitted that fiscal concerns were the only justification for its restrictive coverage criteria, at a public meeting of WHCA's Drug Utilization Review committee meeting:

> "***I can guarantee you that all of us agree that everyone should be treated*** whether they are at stage 2, stage 3, stage 4. However, we have received funding only based on the criteria that we gave for F3…. ***It's out of our hands. None of us would argue that we should not expand it***, that it's not the right thing to do, but we live in a ***political*** environment as a state that ***I have to operate within the resources and rules around those resources that have been given to us***.

Hamburger Decl., *Exh. B*, p. 64 (emphasis added).[10]

---

[8] Most of the costs are paid by the federal government, however. In WHCA's recent budget request, it anticipated that the federal government would pay as much as ***75% of the cost of HCV treatment for Medicaid recipients***. Hamburger Decl., *Exh. A*, pp. 1, 2, 5 (request for $77.7 million, of which $20 million would come from the general fund).

[9] http://www.hca.wa.gov/Documents/budget/2016_PL-P2_Hepatitis_C_Treatment_Expansion.pdf

[10] WHCA's fiscal concerns are not borne out by WHCA's own data. WHCA's exclusionary policy is so overly restrictive that the Medicaid agency ***underspent*** the funds allocated by the Legislative for coverage of DAA medications to treat HCV. Hamburger Decl., *Exh. C (*Budget Adjustment). Those funds, totaling $44 million dollars, could have treated ***2,400 additional Medicaid patients***. Instead, thousands of Medicaid patients with HCV were denied coverage. *See* Hamburger Decl., *Exh. D* (chart on denials).

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

WHCA's policy will cost Washington State more in the long run. Studies have concluded that DAAs, although expensive in the near term, are cost-effective overall when provided to patients with lower fibrosis scores. Gish Decl., ¶ 18. This is because early DAA treatment greatly reduces the cost of treating associated manifestations of HCV, including advanced liver disease and cancer, as well as the public health risk of spreading the disease. *Id.*, ¶¶ 18-19.

F. Plaintiffs Need DAA Prescription Medications to Treat Their Hepatitis C Virus.

Both plaintiffs are enrolled in Washington's Medicaid program, monoinfected with HCV, and have a fibrosis scores of less than F3. Dkt. No. 7, ¶¶ 1-3; Dkt. No. 8, ¶¶ 1-3; Dkt. No. 16, ¶¶ 1-2. The treating medical providers of both B.E. and A.R. prescribed treatment to cure their HCV infections. *Id.* Both plaintiffs' requests were denied because WHCA determined that they did not have "cirrhosis or clinically significant liver fibrosis." Dkt. No. 7, ¶¶ 1-3; Dkt. No. 8, ¶¶ 1-3.

Plaintiff A.R. appealed WHCA's denial to an administrative hearing, which resulted in an initial decision upholding the denial. *Id.*, ¶ 4. A.R. appealed the initial decision to the WHCA Board of Appeals, which issued an Order Remanding Case for a ***second*** administrative hearing, *Id.*, ¶ 5. A.R. remains untreated for his HCV infection nearly a year after his medical provider first requested coverage of Harvoni. Dkt. No. 8, ¶¶ 3-5. B.E.'s provider requested a DAA for her on December 3, 2015, which WHCA denied, leaving her untreated for her HCV infection. Dkt. No. 7, ¶ 3.

III. ARGUMENT

A. Legal Standard for Preliminary Injunction

"A Plaintiff seeking a preliminary injunction must establish that he is [1] likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Am. Trucking Ass'ns v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir. 2009) (quoting *Winter v. Natural Res. Def. Council Inc.*, 129 U.S. 365, 374 (2008)). Where a plaintiff makes a strong

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

showing of irreparable harm and that the injunction is in the public interest, it need not make as great a showing with respect to likelihood of success on the merits. *See Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134-1135 (9th Cir. 2011). If the Court's injunction is "mandatory" rather than "prohibitory," then the plaintiffs must meet the additional burden of showing that the law and facts clearly favor the plaintiffs. *Anderson v. United States*, 612 F.2d 1112, 1114 (9th Cir. 1979) (quoting *Martinez v. Mathews*, 544 F.2d 1233, 1243 (5th Cir.1976)); *see, e.g., A.H.R. v. Wash. State Health Care Auth.*, 2016 U.S. Dist. LEXIS 2587, at *38, 62-63 (W.D. Wash. Jan. 7, 2016) (issuing a mandatory injunction against WHCA on behalf of Medicaid recipients who need access to in-home skilled nursing care).

On behalf of the proposed class, plaintiffs request that the Court enjoin WHCA from continuing to apply its February 25, 2015 HCV treatment policy, including its exclusion of all treatment based upon fibrosis score, and to require WHCA to return to providing coverage for prescription medications to treat HCV without regard to fibrosis score, consistent with existing state and federal Medicaid requirements.

B. Plaintiffs Are Likely to Succeed on the Merits.

Plaintiffs' Complaint invokes three distinct provisions of Title XIX of the Social Security Act ("Medicaid Act"): 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396a(a)(10)(B) (as codified at 42 C.F.R. § 440.240); and 42 U.S.C. § 1396a(a)(8); Dkt. No. 1, ¶¶ 37-42. The first provision requires the defendant to make "medical assistance" available, including medically necessary prescription drugs, to eligible Medicaid enrollees, such as plaintiffs and the putative class. *See Watson v. Weeks*, 436 F.3d 1152, 1159 (9th Cir. 2006). This section thus "prohibits states from denying coverage of 'medically necessary' services that fall under a category covered in their Medicaid plans." *Alvarez v. Betlach*, 572 F. App'x 519, 521 (9th Cir. 2014) (citing, *inter alia*, *Beal v. Doe*, 432 U.S. 438, 444 (1977)). The second statutory provision creates the obligation of "Medicaid comparability," which "mandates comparable services for individuals with comparable needs and is violated when some recipients are treated differently than others where

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

each has the same level of need." *Dunakin v. Quigley*, 99 F. Supp. 3d 1297, 1321 (W.D. Wash. 2015). The third section compels the defendant to furnish medical assistance "with reasonable promptness to all eligible individuals." *Id.*, 99 F. Supp. 3d at 1320.

Although the Court need only find that plaintiffs are likely to succeed on one of these claims in order to enjoin the defendant, plaintiffs are likely to succeed on all three.

1. *First Claim:* The Medicaid Act Requires Coverage of Medically Necessary HCV Prescription Drug Treatment.

Medicaid is a cooperative federal and state program under which the State of Washington chooses to accept federal funds to support the provision of medical care to low-income individuals like B.E. and A.R. 42 U.S.C. § 1396; *S.A.H. ex rel. S.J.H. v. Dep't of Soc. & Health Servs.*, 136 Wn. App. 342, 348, 149 P.3d 410 (2006). While participation in the Medicaid program is voluntary, once a state has chosen to participate, it must comply with all Medicaid statutes and regulations. *Id.* The single state agency responsible for the implementation of Medicaid, the WHCA, may authorize rules and policies consistent with the requirements of the federal Medicaid statute and regulations. *Id.; see* RCW 74.04.055; 74.08.090.

The Medicaid Act requires participating states to make medical assistance available to qualified individuals for certain mandatory services under 42 U.S.C. § 1396a(a)(10)(A) as well as offering a set of services that states may opt into, including prescription drug coverage. 42 U.S.C. § 1396d(a)(12). Washington, like all other states, has opted to provide prescription drug coverage in its Medicaid program. Hamburger Decl., *Exh. E* (state Medicaid Plan); *Exh. F* (CMS guidance), p. 1.

Having opted to provide coverage for prescription drugs, Washington's Medicaid program must adhere to the Medicaid Act's specific strictures regarding prescription drugs. *See* 42 U.S.C. § 1396a(a)(54). Among these requirements is coverage for any outpatient drug prescribed by a provider for an indicated purpose approved by the FDA, and for which the drug manufacturer has entered into a rebate agreement. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

(2003); 42 U.S.C. §§ 1396r-8(a)(1), 1396r-8(d), 1396r-8(k). There is no dispute that DAA drugs are approved for treatment of HCV by the FDA or that the manufacturers of these medications have entered into the required rebate program. Without such requirements, WHCA could not cover DAAs at all.

The sole pretext for denying DAA treatment to plaintiffs and the putative class arises from the concept of medical necessity. Medical necessity is the "touchstone" of the Medicaid Act. *Allen v. Mansour,* 681 F. Supp. 1232, 1237 (E.D. Mich. 1986), *citing Pinneke v. Preisser*, 623 F.2d 546, 548 n. 2 (8th Cir. 1980). States are prohibited from "denying coverage of medically necessary services that fall under a category covered in their Medicaid plans." *Alvarez,* 572 F. App'x at 521 (citing 42 U.S.C. § 1396a(a)(17) and 42 C.F.R. § 440.230(d)). In Washington, "medical necessity" was established pursuant to a consent decree in *Mead v. Burdman.*[11] Hamburger Decl., *Exh. G,* Consent Order, pp. 2-3. That definition was imported into the Washington Administrative Code at 182-500-0070. Medical necessity means:

> [A] term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction.

WAC 182-500-0070. For the purpose of that rule, WHCA defines "course of treatment" to include "mere observation" or "no medical treatment at all." *Id.*

WHCA has established the procedure for determining "medical necessity" of prior authorized treatment, including prescription medications, in WAC 182-501-0165. That rule requires WHCA to first determine the quality of the clinical evidence to support the use of the treatment. If the level of evidence is rated "A" or "B," then WHCA is required to cover the

[11] That litigation and subsequent contempt actions arose out of the State's prior efforts to inject fiscal concerns into the medical necessity determinations under the Medicaid program. Hamburger Decl., *Exh. H,* p. 2.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

medication ***unless*** the agency identifies an "equally effective alternative treatment" that does not place the enrollee "at greater risk of mortality or morbidity" ***and*** the alternative treatment is not more costly. WAC 182-501-0165(6)(c)(i)(A), (B) . Both conditions must be met in order for WHCA to deny access to a covered medication with an "A" or "B" level of evidence of effectiveness. *Id.*

It is undisputed that DAAs like Harvoni are rated at an "A" or "B" level of evidence. Gish Decl., ¶ 14 (the AASLD-IDSA rates the evidence at level "A"); WHCA concedes that there is no equally effective alternative medication to treat HCV. Dkt. No. 16, ¶¶ 1-2. The only "treatment" WHCA offers as an alternative is "observation," or in other words, no medical treatment at all. WHCA's blanket exclusion of DAAs for monoinfected Medicaid recipients with an F0-F2 fibrosis score is only permissible under state and federal Medicaid law if WHCA can show that "mere observation" (1) is an equally effective alternative treatment to curative treatment with a DAA, and (2) does not place Medicaid enrollees with HCV at greater risk of mortality or morbidity. WHCA cannot show that either prong is met.

First, it should go without saying that a cure for a life-threatening disease is more effective than mere observation. Observation alone will never cure plaintiffs or putative class members of their chronic HCV. In fact, it may kill them. Gish Decl., ¶¶ 10, 17. From a public health perspective, mere observation leaves them infected with a highly communicable, often deadly disease, at risk of infecting others. Gish Decl., ¶¶ 4, 19. Observation is not an "equally effective" alternative to a likely cure of HCV.

Second, even if observation includes an implied promise of future coverage, the availability of coverage once a recipient's liver is damaged is not a form of "equally effective alternative treatment." As Dr. Gish explains, waiting until a Medicaid enrollee's liver is damaged before providing treatment is harmful to his/her health and significantly increases the risk of both morbidity and mortality:

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

- Delaying treatment ***decreases*** the long-term survival rate for HCV patients. Gish Decl., ¶ 8 (citing to the AASLD-IDSA guidance, which in turn cites to multiple studies). ***"[W]aiting to treat HCV infection at Metavir fibrosis stages F3 and F4 resulted in a 2- and 5- times higher rates of liver-related mortality***, respectively, compared with treating at Metavir stage F2." *Id.* (emphasis added)

- Delay significantly increases the risk of cancer. "Once a person reaches a fibrosis score of F3 or F4 his or her chance of getting liver cancer is so significant that it is recommended that, even after having been cured with a DAA, the individual undergo twice yearly liver surveillance for liver cancer." *Id.*, ¶ 17 (emphasis in original).

- Waiting increases the risk of extra-hepatic symptoms and conditions. Medicaid enrollees who do not receive immediate treatment are "needlessly exposed to health conditions caused by HCV, including cirrhosis, cancer, heart attacks, fatigue, joint pain, depression, sore muscles, arthritis, death and unneeded liver transplants and jaundice." *Id.*, ¶ 10.

- Dr. Gish concludes that observation without treatment falls so far below the standard of medical care as to be unethical and could be deemed malpractice. *Id.*, ¶16. The AASLD-IDSA has concluded that there is "no medical evidence to justify that position [waiting to treat HCV patients] and much to justify treating all patients. *Id., Exh. C.*

- Delaying treatment risks spreading this communicable disease to others, including family members. *Id.*, ¶ 17. In other words, delay prevents or significantly slows the eventual eradication of this deadly disease.

Early treatment of HCV is the standard of care in Washington State. More than fifteen leading local liver specialists, physicians and Chief Medical Officers of some of Washington's major health care systems all agree: restrictions on anti-viral treatment for HCV must be removed. Gish Decl., *Exh. E.* The Washington physicians argued that such restrictions "frustrate the medical judgment of practicing physicians [who are] treating patients …." *Id.*, p. 2. They concluded that "[t]here is no medical basis for the … coverage restrictions." *Id.* Indeed, since

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

the local physicians issued this letter, every major insurer in the State of Washington now covers DAA medications without fibrosis scoring.[12] Hamburger Decl., ¶ 11.

Third, WHCA presumably prefers observation to curative treatment because it is less costly, even though it is not "equally effective." Cost concerns cannot usurp WHCA's obligations under the Medicaid Act to pay for "medically necessary" covered services. *Alvarez v. Betlach*, 2012 U.S. Dist. LEXIS 190191, at *20 (D. Ariz. May 21, 2012) ("States must provide medically necessary home health services to individuals entitled to those services … irrespective of cost."), affirmed in relevant part in *Alvarez v. Betlach*, 572 F. App'x 519, 521 (9th Cir. 2014). *Beal v. Doe*, 432 U.S. 438, 444-45, 97 S. Ct. 2366 (1977) ("serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage"). *See also Weaver v. Reagen*, 886 F.2d 194, 197-98 (8th Cir. 1989) (a state Medicaid plan must provide treatment that is "medically necessary" in order to comport with the objectives of the Medicaid Act). While the Court may take the State's potential budgetary concerns into consideration, these concerns cannot be the sole basis for restricting medically necessary coverage. "[A] state may not ignore the Act's requirements in order to suit state budgetary needs." *Parents League for Effective Autism Servs. v. Jones-Kelley*, 565 F. Supp. 2d 905, 911 (S.D. Ohio 2008); *see also Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1499, n. 3 (9th Cir. 1997); *Beno v. Shalala*, 30 F.3d 1057, 1069, n. 30 (9th Cir. 1994); *Arkansas Medical Soc., Inc. v. Reynolds*, 6 F.3d 519, 531 (8th Cir. 1993) (*citing cases*). Without any clinical justification, WHCA's rationing is impermissible.

Fourth, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency responsible for administering Medicaid has rejected Washington's exclusionary policy. On November 5, 2015, CMS issued a Medicaid Drug Rebate Program Notice entitled "Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs," which "addresses utilization of the

[12] In early February, Regence, BridgeSpan and Group Health still used the same exclusionary criteria that HCA is using. Just three weeks after similar litigation was filed, all three repealed the exclusions, allowing coverage of HCV medications regardless of fibrosis score. Hamburger Decl., ¶ 11.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

[DAA] drugs approved by the [FDA] for the treatment of chronic HCV infected patients." *See* Hamburger Decl., *Exh. F* ("Guidance"). The Guidance is direct and express:

> CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in [42 U.S.C. § 1396r-8(d)] by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, ***several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to fibrosis score F3***….
>
> [T]he effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

Id., pp. 2-3 (emphasis added). CMS's interpretation of the requirements of the Medicaid Act is entitled to deference based upon "the agency's expertise, the statute's complexity and technical nature, and the broad authority delegated to the Secretary of Health and Human Services under the Act." *Katie A. v. L.A. Cnty.*, 481 F.3d 1150, 1155, n. 11 (9th Cir. 2007). Despite the CMS directive, WHCA has refused to rescind its rationing policy.

In sum, WHCA's blanket exclusion of all coverage of DAAs for monoinfected Medicaid recipients with HCV when their fibrosis score is F0 to F2 violates the Medicaid Act. Plaintiffs and the putative class are entitled to coverage for covered Medicaid services when those services are medically necessary. Treatment of HCV with DAAs is medically necessary, and there is no equally effective, less costly alternative treatment. WHCA's proposed alternative – observation without treatment – significantly increases the risk of mortality or morbidity of Medicaid recipients and does not provide a cure. Plaintiffs and the putative class are likely to succeed on their first claim.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

2. *Second Claim:* HCA's Coverage Policy Fails to Ensure Reasonably Prompt Care.

Under Washington's Medicaid program, if the treatment is covered and medically necessary, it must also be furnished with "reasonable promptness to all eligible individuals." *Dunakin v. Quigley*, 99 F. Supp. 3d 1297, 1320 (W.D. Wash. 2015), *quoting* 42 U.S.C. § 1396a(a)(8). Courts have interpreted this provision to require payment or provision of services without unreasonable delay, typically not to exceed ninety days. *Doe 1-13 By & Through Doe, Sr. 1-13 v. Chiles*, 136 F.3d 709, 721-22 (11th Cir. 1998); *Boulet v. Cellucci*, 107 F. Supp. 2d 61, 82 (D. Mass. 2000).

Lengthy wait times for medically necessary treatment have been rejected by courts as violating the Medicaid Act's "reasonable promptness" requirement. For example, in *Allen v. Mansour*, the court found a two-year abstinence waiting period for a liver transplant was unreasonable because the waiting period was not imposed based upon any clinical evidence. *See Allen*, 681 F. Supp. at 1238. Instead, the waiting period impermissibly excluded a large group of Medicaid recipients from ever getting the liver transplant they need to survive. *Id*. Similarly here, WHCA's policy imposes an unreasonable delay on the provision of medically necessary treatment, in violation of the Medicaid Act. The policy places plaintiffs and class members into a period of indefinite limbo, during which they are left to suffer through the extrahepatic effects of their disease. It is not grounded in clinical recommendations or expertise. The policy leaves plaintiffs and the putative class waiting for medically necessary covered prescription medications well beyond 90 days, and quite possibly for years. Plaintiffs are likely to succeed on the merits of their "reasonable promptness" claim.

3. *Third Claim*: HCA's Coverage Policy Violates Medicaid's Comparability Requirement.

The Medicaid Act's "comparability" requirement provides that Medicaid coverage made available to an individual "shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual ...." *Jenkins v. Washington State Dep't of*

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

Soc. & Health Servs., 160 Wn.2d 287, 296, 157 P.3d 388 (2007), *quoting* 42 U.S.C. § 1396a(a)(10)(B)(i) and *citing* 42 C.F.R. § 440.240; *Samantha A. v. Dep't of Soc. & Health Servs.*, 171 Wn.2d 623, 631, 256 P.3d 1138 (2011). Stated plainly, comparable Medicaid enrollees must be treated comparably. The WHCA Policy runs afoul of this requirement by excluding certain Medicaid enrollees with HCV from medically necessary DAA treatment, while providing the same treatment to other Medicaid enrollees with HCV.

In both *Jenkins* and *Samantha A.*, the Washington Supreme Court struck down the State Medicaid agency's use of categorical presumptions that excluded or limited Medicaid enrollees from coverage for Medicaid services without regard to their actual, individualized medical need for such service. *Jenkins*, 160 Wn.2d at 300; *Samantha A.*, 171 Wn.2d at 631. The Supreme Court concluded that Washington's Medicaid agency must make individualized determinations of medical necessity, rather than relying on across-the-board limitations and exclusions. *Id.* Similarly here, plaintiffs and the putative class are likely to succeed in striking down the WHCA Policy that categorically excludes all monoinfected enrollees with a fibrosis score of less than F3 from DAA treatment without any determination of whether their individualized medical needs warrant earlier treatment. Plaintiffs are likely to prevail on the merits of their comparability claim.

C. Absent Immediate Relief, Plaintiffs Will Suffer Irreparable Harm.

The loss of necessary Medicaid services constitutes *per se* irreparable harm. *Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004); *Beltran v. Myers*, 677 F.2d 1317, 1322 (9th Cir. 1982). "[D]elay or denial of Medicaid benefits can amount to irreparable harm." *Markva v. Haveman*, 168 F. Supp. 2d 695, 719 (E.D. Mich. 2001) (recognizing the principle that the "risk of further injury to health warrants injunctive relief"); *see also Daniels v. Wadley*, 926 F. Supp. 1305, 1313 (M.D. Tenn. 1996), *vacated in part on other grounds sub nom Daniels v. Menke*, 145 F.3d 1330 (6th Cir. 1998) (injunction granted to prevent Medicaid recipients from suffering physical harm due to delayed medical care); *Kai v. Ross*, 336 F.3d 650, 656 (8th Cir. 2003) (danger to plaintiff's health presents a "strong argument of irreparable injury"); *Caldwell v. Blum*, 621 F.2d 491, 498

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

(2d Cir. 1980) (holding that Medicaid applicants established harm where they would "absent relief, be exposed to the hardship of being denied essential medical benefits"); *McMillan v. McCrimon*, 807 F. Supp. 475, 479 (C.D. Ill. 1992) (holding that "[t]he nature of their claim – a claim against the state for medical services – makes it impossible to say that any remedy at law could compensate them"). Reduction of necessary medical benefits directly impacts an individual's health, creating "(1) substantial risk to plaintiffs' health; (2) severe financial hardship; (3) the inability to purchase life's necessities; and (4) anxiety associated with uncertainty." *LaForest v. Former Clean Air Holding Co., Inc.*, 376 F.3d 48, 55 (2d Cir. 2004) (affirming the issuance of a preliminary injunction regarding medical benefits).

It is undisputed that plaintiffs and all of the proposed class members are blocked from obtaining an individualized review of their need for HCV treatment due to WHCA's blanket exclusion of HCV treatment. All have suffered a loss of coverage for services that they are all likely to need. If the exclusionary policy is lifted, each class member will be entitled to an individualized review of their need for HCV treatment.

The loss of medically necessary Medicaid coverage alone is irreparable harm. Here, however, plaintiffs and the class show that if they continue to be excluded from medically necessary treatment, they are at imminent risk of deteriorating health, liver damage and even death:

> Delaying treatment by observation has a variety of adverse effects including increasing the risk of death, causing irreversible liver damage, and needlessly prolonging suffering associated with the disease. From a public health perspective, observation without treatment risks spreading the disease to others, including family members. ***There is simply no medical justification for observation and delaying treatment to an individual who otherwise meets the AASLD and IDSA Guidelines.*** On the contrary, it is critical that patients with chronic HCV be treated before the liver has been damaged by the virus. ***Delaying treatment and observing an individual while that individual's liver degrades to a fibrosis score of F3 or F4 significantly increases the risk of death from cancer***

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

> ***or liver failure. It also significantly increases the chance that the individual will require a liver transplant***.

Gish Decl., ¶ 17 (emphasis added). The deterioration described in Dr. Gish's declaration and in the studies cited is not purely theoretical. Putative class members are already suffering from WHCA's exclusionary policy. For example, Northwest Justice Project attorney Elizabeth Landry recounts one client, L.B., whom she represented in an administrative hearing to try to obtain HCV treatment. Landry Decl., ¶¶ 2-8. His treating provider recommended treatment with Harvoni in May 2015. *Id.* His treatment was denied by WHCA because his fibrosis score was too low. *Id.* While his Medicaid administrative appeal was pending, his kidneys deteriorated so significantly that his provider could no longer recommend him for treatment with Harvoni. *Id.*, ¶ ¶ 7. It is unclear whether his health will ever improve sufficiently to be eligible again for treatment for HCV. *Id.* Thus, for some class members, continued delay could mean that the window of opportunity for a cure closes, perhaps forever.

D. The Balance of Hardships Tips Sharply in the Plaintiffs' Favor.

The medical needs of plaintiffs and the class heavily outweigh state budget constraints. As the Ninth Circuit recently stated in *M.R. v. Dreyfus*, "[w]e have several times held that the balance of hardships favors beneficiaries of public assistance who may be forced to do without needed medical services over a state concerned with conserving scarce resources." 697 F.3d 706, 737-38 (9th Cir. 2012). Further, the potential costs to the state do not outweigh the harm resulting from prohibiting recipients from accessing those needed benefits.

> Plaintiffs do not attempt to match in dollars and cents the monetary harms that will allegedly be suffered by the government. Yet the physical and emotional suffering shown by plaintiffs in the record before us is far more compelling than the possibility of some administrative inconvenience or monetary loss to the government.

Lopez v. Heckler, 713 F.2d 1432, 1437 (9th Cir. 1983). Where the government's actions cause a loss of life's necessities, further illness, or other deprivation to the plaintiffs, the balancing of the hardships tips "decidedly" in their favor. *Id.* When an injunction requires defendant to comply

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

with existing law, as does the injunction sought by plaintiffs here, the injunction imposes no burden but "merely seeks to prevent the defendants from shirking their responsibilities under it." *Haskins v. Stanton*, 794 F.2d 1273, 1277 (7th Cir. 1986). The balancing of hardships strongly favors the plaintiffs.

E. The Injunction Will Advance the Public Interest.

"[T]here is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as the most needy in the country." *M.R.*, 697 F.3d at 738, *citing Indep. Living Ctr. of S. California, Inc. v. Maxwell-Jolly*, 572 F.3d 644, 659 (9th Cir. 2009), *vacated and remanded on other grounds by Douglas v. Indep. Living Ctr. of S. California, Inc.*, 132 S. Ct. 1204, 182 L. Ed. 2d 101 (2012). Moreover, these is no public interest in permitting defendant to continue to violate the Medicaid Act. *Nat'l Wildlife Fed. v. Nat'l Marine Fisheries Serv.*, 235 F. Supp. 2d 1143, 1162 (W.D. Wash. 2002) ("[E]nsuring that government agencies comply with the law is a public interest of the highest order"). The public interest is particularly acute when dealing with a communicable disease. Gish Decl., ¶ 19 ("Delaying treatment undermines this important public health goal [of disease eradication]."). Issuing an injunction to prevent WHCA from applying its exclusionary policy will advance the public interest.

IV. THE COURT SHOULD NOT REQUIRE A BOND.

Federal courts routinely exercise their discretion under FRCP 65(c) to waive the bond requirements in suits to enforce important federal rights or public interests. *Barahona-Gomez v. Reno*, 167 F.3d 1228, 1237 (9th Cir. 1999). This is so particularly where, as here, the plaintiffs and the proposed class are recipients of public assistance. *See id.* at 1237. Moreover, important federal rights are at stake in this litigation. *See, e.g., Temple Univ. v. White*, 941 F.2d 201, 220 n. 27 (3d Cir. 1991) ("Public policy under [federal law governing state modification of Medicaid programs] mandates that parties in fact adversely affected by improper administration of program pursuant thereto be strongly encouraged to correct such errors." Given the high likelihood of

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246

success on the merits, plaintiffs' status as public assistance recipients, and the fact that the injunction seeks merely to require defendant to comply with state and federal Medicaid requirements, no bond should be required.

V. CONCLUSION

The Court should order defendant to cease applying the WHCA policy and all denials of coverage for DAA treatment based upon fibrosis score, for the duration of this litigation.

DATED: March 18, 2016.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER

/s/ Richard E. Spoonemore
Richard E. Spoonemore (WSBA #21833)
Eleanor Hamburger (WSBA #26478)

COLUMBIA LEGAL SERVICES

/s/ Amy L. Crewdson
Amy L. Crewdson (WSBA #9468)
711 Capitol Way South, #304
Olympia, WA 98501
Telephone: (360) 943-6585, Ext. 214

HARVARD LAW SCHOOL CENTER FOR HEALTH LAW & POLICY INNOVATION

/s/ Kevin Costello
Kevin Costello (admitted *pro hac vice*)
122 Boylston Street
Jamaica Plain, MA 02130
Telephone: 617-390-2578

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on March 18, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

- **Angela D. Coats McCarthy**
  AngelaC3@atg.wa.gov, ChristineH1@atg.wa.gov,VivianB@atg.wa.gov, NicoleB3@atg.wa.gov
- **Kevin Costello**
  kcostello@law.harvard.edu, dilseysays@hotmail.com
- **Amy Louise Crewdson**
  amy.crewdson@columbialegal.org, fanny.cordero@columbialegal.org
- **Eleanor Hamburger**
  ehamburger@sylaw.com, matt@sylaw.com, theresa@sylaw.com
- **Nissa Ann Iversen**
  NissaI@atg.wa.gov, christineh1@atg.wa.gov, VivianB@atg.wa.gov, NicoleB3@atg.wa.gov
- **Richard E Spoonemore**
  rspoonemore@sylaw.com, matt@sylaw.com, rspoonemore@hotmail.com, theresa@sylaw.com

DATED: March 18, 2016, at Seattle, Washington.

/s/ Eleanor Hamburger
Eleanor Hamburger (WSBA #26478)

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER
999 THIRD AVENUE, SUITE 3650
SEATTLE, WASHINGTON 98104
TEL. (206) 223-0303 FAX (206) 223-0246